

**Environmental Assessment for Marketing Order for a New  
Roll-Your-Own Cigarette Paper by BBK Tobacco & Foods LLP,  
Company D/B/A/ HBI International**

**Prepared by Center for Tobacco Products  
U.S. Food and Drug Administration**

**March 23, 2020**

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**1. Applicant and Manufacturer Information**

<b>Applicant Name:</b>	BBK Tobacco & Foods, LLP Company d/b/a HBI International
<b>Applicant Address:</b>	3401 West Papago Street Phoenix, AZ 85009
<b>Manufacturer Name:</b>	BBK Tobacco & Foods, LLP Company d/b/a HBI International
<b>Products Manufacturing Address:</b>	See Confidential Appendix 1.

**2. Products Information**

**New Product Submission Tracking Number (STN), Name, and Predicate Product Name**

<b>STN</b>	<b>New Product Name</b>	<b>Predicate Product Name</b>
SE0015653	Raw Classic Rolls Single Wide	Elements Rolls Ultra Thin Single Wide

**Product Identification**

<b>Product Category</b>	Roll-Your-Own
<b>Product Subcategory</b>	Rolling Paper
<b>Product Package</b>	Consists of a paperboard box with foldable lid, five meters of uncut rolling paper coiled around a paperboard spool, each paperboard box has a polypropylene film overwrap. One display case contains 24 boxes.

**3. The Need for the Proposed Action**

The proposed action, requested by the applicant, is for U.S. Food and Drug Administration (FDA) to issue a marketing order under the provisions of sections 910 and 905(j) of the Federal Food, Drug, and Cosmetic Act. The applicant wishes to introduce one new roll-your-own (RYO) product into interstate commerce and submitted to the Agency a substantial equivalence (SE) report. The Agency shall issue a marketing order if the new product is found substantially equivalent to the predicate product. The new and predicate products are currently being marketed. The predicate product, a grandfathered product, was marketed as of February 15, 2007. . The applicant intends to market the new and predicate products simultaneously after the new product receives a marketing order. The difference between the new and predicate products is the new product is packaged in a paperboard box and the predicate product is packaged in a plastic box.

#### 4. Alternatives to the Proposed Action

The no-action alternative is FDA does not issue a marketing order for the new tobacco product in the United States.

#### 5. Potential Environmental Impacts of the Proposed Action and Alternatives – Manufacturing the New Product

The Agency considered potential impacts to resources in the environment that may be affected by manufacturing the new product and found no significant impacts.

##### 5.1 Affected Environment

The new and predicate products are manufactured in foreign facilities (Confidential Appendix 1). The manufacturing facilities are located in mixed-use industrial areas consisting of warehouses, and light manufacturing facilities.

##### 5.2 Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from manufacturing the new product based on information gathered by the Agency and the information in the SE Report, including projected market volumes for the new product (Confidential Appendix 2).

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that manufacturing the new product is not expected to result in changes to air emissions or require additional environmental controls for air emissions. According to the applicant, overall manufacturing at the facility is not expected to increase as result of manufacturing the new product.
Water resources	The Agency does not anticipate that manufacturing the new product would cause any new chemicals to be discharged into the water. The applicant stated that manufacturing the new product is not expected to result in changes to wastewater discharges or require any additional environmental controls.
Soil, land use, and zoning	The applicant stated that there would be no facility expansion due to manufacturing the new product. Therefore, there would be no zone change or land conversion of prime farmland, unique farmland, or farmland of statewide importance to non-agricultural use.
Biological resources	The applicant stated that there would be no facility expansion. Therefore, the Agency does not anticipate that manufacturing the new product would jeopardize the continued existence of any listed species or result in adverse effects on species or habitats addressed under the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES).
Socioeconomic conditions	There would be no expected impacts on employment, revenue, taxes, or community resources because the new product is intended to compete with and eventually replace similar tobacco products currently manufactured at the facility.

Solid waste and hazardous materials	The Agency does not foresee that the introduction of the new product would noticeably affect the current manufacturing waste generated from the production of all RYO product at this facility. The waste generated due to manufacturing the new product would be released to the environment and disposed of in landfills in the same manner as the waste generated from any other product manufactured in the same facility. The manufacturer's compliance with applicable environmental regulations is assumed to indicate no significant impacts would occur.
Floodplains, wetlands, and coastal zones	There would be no facility expansion due to manufacturing the new product and the applicant did not propose any land disturbance; therefore, there would be no effects on floodplains, wetlands, or coastal zones.
Regulatory compliance	The applicant stated that the manufacturing facility is in compliance with all applicable environmental regulations, including CITES.

### 5.3 Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts due to the manufacturing of the new product.

### 5.4 Impacts from No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of manufacturing RYO tobacco products, as many similar RYO tobacco products would continue to be manufactured at the same facility.

## 6. Potential Environmental Impact of the Proposed Action and Alternatives – Use of the New Product

The Agency considered potential impacts to resources in the environment that may be affected by use of the new product and found no significant impacts.

### 6.1. Affected Environment

The affected environment is the entire United States because the marketing order would allow for the new tobacco product to be sold to consumers nationwide. The new RYO tobacco product is intended to be cut, rolled, and filled with tobacco by users who may smoke them indoors or outdoors, as the law permits.

### 6.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential environmental impacts from use of the new product based on information gathered by the Agency and the applicant-submitted information.

Environmental Resource	Analysis of Potential Impacts
Air quality	The applicant stated that the market volume predictions are a fraction of a percent of the total predicted cigarette sales in the United States. In addition, the new and predicate products differ only in the packaging. Therefore, the

	Agency does not anticipate that using the new product would lead to the release of new chemicals into the air, as compared to the predicate product or similar currently marketed products.
Environmental justice	The new product is expected to be used by the same consumers that use the predicate product. Therefore, no changes in impacts to environmental justice populations are anticipated.

### 6.3. Cumulative Impacts

The Agency did not identify any actions that would lead to cumulative impacts due to the use of the new product.

### 6.4. Impacts from No-Action Alternative

The environmental impacts of the no-action alternative would not change the existing condition of use of RYO tobacco products, as many similar tobacco products would continue to be marketed and therefore used in the United States.

## 7. Potential Environmental Impacts of the Proposed Action and Alternatives – Disposal of the New Product

The Agency considered potential impacts to resources in the environment that may be affected by disposal of the new product and found no significant impacts.

### 7.1. Affected Environment

The affected environment is the entire United States because the marketing order would allow for the new tobacco product to be sold to consumers nationwide. The disposal would be via municipal solid waste (MSW) landfills, recycling centers, or as litter.

### 7.2. Analysis of Potential Environmental Impacts

The Agency evaluated the proposed action for potential impacts from disposal of the new product based on information submitted in the SE Report, including market volume projections for the new product (Confidential Appendix 2).

Environmental Resource	Analysis of Potential Impacts
Air quality	Introducing the new product into the U. S. market is not expected to increase the nationwide use of RYO tobacco products; therefore, disposal of the used product and packaging would not significantly affect air quality.
Biological resources	Proper disposal of the new product and its packaging materials in MSW would not affect biological resources. Used product and packaging materials may be littered in undeveloped areas and wildlife habitat. However, introducing the new product into the U. S. market is not expected to increase the nationwide use of RYO tobacco products based on the Agency's assessment. Therefore,

	littering levels are not expected to change from the current levels due to existing tobacco products.
Environmental justice	No significant environmental impacts associated with the disposal of the new product and packaging materials were identified; therefore, no disproportionate impacts to environmental justice populations are anticipated.
Water resources and water quality	Proper disposal of used new product and packaging materials in the MSW stream would not affect water resources. Improper disposal could occur in or near surface water. However, introducing the new product into the U. S. market is not expected to increase the nationwide use of RYO tobacco products, based on the projected market volumes reported by the applicant (Confidential Appendix 2). Therefore, littering levels are not expected to change from the current levels due to existing tobacco products.
Regulatory compliance	It is assumed that littering of the new product and packaging waste, despite state and local ordinances, would be no greater than the littering rate of the currently marketed RYO tobacco products.

**7.3. Cumulative Impacts**

The Agency did not identify any actions that would lead to cumulative impacts due to the disposal of the new product.

**7.4. Impacts from No-Action Alternative**

The environmental impacts of the no-action alternative would not change the existing condition of disposal of RYO tobacco products, as many similar tobacco products would continue to be marketed and therefore disposed of in the United States.

## **8. List of Preparers**

The following individuals were primarily responsible for preparing and reviewing this environmental assessment:

### ***Preparer:***

Thomas E. Creaven, Ph.D., Center for Tobacco Products

Education: B.S. in Chemistry/Biology, Ph.D. in Biology/Neuroscience

Experience: Ten years in science education and three years in NEPA Review

Expertise: Physics, Chemistry, Biology education and NEPA Review

### ***Reviewer:***

Hoshing W. Chang, Ph.D., Center for Tobacco Products

Education: Ph.D. in Biochemistry, M.S. in Environmental Science

Experience: Eleven years in FDA-related NEPA review

Expertise: NEPA analysis, environmental risk assessment, wastewater treatment

## **9. List of Agencies and Persons Consulted**

Not applicable.



**Confidential Appendix 1**

**Location of Manufacturing Facilities**

The cigarette papers and packaging papers are milled in (b) (4) located at

(b) (4)

(b) (4)

The cigarette papers are cut to size, gummed, converted to paper rolls after the watermark is applied to the paper, and packaged by (b) (4)

(b) (4)

(b) (4)

CONFIDENTIAL APPENDIX 2.

Market Volume Projections for the New and Predicate Products

STN	Market Volume Projection		
	Unit	First Year	Fifth Year
Predicate Product	Number of Rolls	(b) (4)	
	Weight (kg)		
SE0015653	Number of Rolls		
	Weight (kg)		